

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROQUETTE FRERES

Plaintiff,

SPI PHARMA, INC.,

Defendant.

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C. A. No. 06-540 GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 5,573,777

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 5,573,777 (the “777 patent”):

1. The term “pulverulent mannitol” is construed to mean “a powder, having a mannitol richness calculated with respect to the amount of sugars or polyols present, of at least 90%.”¹

¹ “[C]laims ‘must be read in view of the specification, of which they are a part.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2006) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995)). As the Federal Circuit has advised, “the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Phillips*, 415 F.3d at 1315 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Here, the written description of the ‘777 patent uses language that leads the court to conclude that the pulverulent mannitol must be “relatively pure,” and the ‘777 patent defines “relatively pure” as “a mannitol richness, calculated with respect to the amount of sugars or polyols present, of at least 90%.” (‘777 patent, col. 4, ll. 52-54.) Indeed, the written description refers to relatively pure pulverulent mannitol as “the present invention” or “the invention” three times:

The invention relates to a relatively pure pulverulent mannitol . . . (‘777 patent Abstract.)

The present invention, therefore, relates to a relatively pure pulverulent mannitol. . . (Id. col. 4, ll. 34-35.)

From the viewpoint of its chemical composition, the pulverulent mannitol in accordance with the present invention is relatively pure, that is to say that it has a

2. The term “according to a Test I of between about 40% and about 80%” is construed to mean “according to a Test I of between about 40% and about 80%.”²
3. The term “mechanical action in a ERWEKA TAP friabilimeter” is construed to mean “mechanical action in the ERWEKA TAP model of friability testing machine.”³
4. The term “the test on a sieve with mesh size of 100 microns” is construed to mean “[the friability according to this test being a percentage of powder not retained after] the test on a sieve with a mesh size of 100 microns.”⁴
5. The term “a rate of dissolution according to a Test II of between about 0 and about 30 seconds” is construed to mean “a rate of dissolution according to a Test II of approximately 30 seconds or less.”⁵

high mannitol richness. (Id. col. 6, ll. 34-37.)

Further, the written description does not indicate that relatively pure pulverulent mannitol is merely a preferred embodiment. To the contrary, Example 1 describes the preparation of a pulverulent mannitol in accordance with the invention and states that the pulverulent mannitol obtained from the preparation process has “a mannitol richness of 98.9%.” (Id. col. 10, l. 19.) In addition, Example 3, a comparison of tablets obtained by employing pulverulent mannitol according to the invention with those obtained according to the prior art, states that Product V is “[p]ulverulent mannitol according to the invention described in example 1.” (Id. col. 12, ll. 40-41.) Thus, the court concludes that the claimed pulverulent mannitol should be given a narrow construction in light of the ‘777 patent’s written description. *See Honeywell Intern., Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006).

² “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314 (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)).

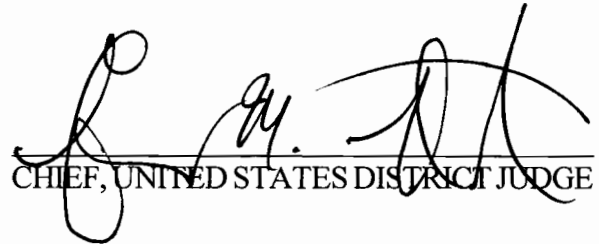
³ The defendant proposed no construction for this claim term. Thus, the court adopts the plaintiff’s proposed construction.

⁴ See footnote 3.

⁵ See footnote 2.

6. The term “introducing into about 150 g of demineralized and degassed water maintained at about 20°C and subjected to stirring at 200 rpm in a 250 ml low form beaker, exactly 5 g of a particle size cut, within the range of about 100 and 200 microns, of the powder to be tested” is construed to have its plain and ordinary meaning.⁶
7. The term “perfect visual clarity of the suspension thus prepared” is construed to mean “the point at which the powder introduced is no longer visible in the water.”⁷
8. The term “comprising a mannitol richness . . . greater than approximately 90%” is construed to mean “comprising a mannitol richness which is greater than 90%.”⁸
9. The term “atomizing” is construed to mean “reducing to fine particles.”⁹
10. The term “granulating by a wet route” is construed to mean “causing particles to agglomerate in a wet environment.”¹⁰

Dated: June 11, 2010



CHIEF, UNITED STATES DISTRICT JUDGE

⁶ Id. Further, the defendant notes in its briefing that the parties agree on the construction.

⁷ See footnote 2.

⁸ The court adopts the defendant’s proposed construction based on its construction of the term “pulverulent mannitol.” See footnote 1. The plaintiff argues that the defendant’s construction renders claim 16, which is dependent on claim 1 and claims a mannitol richness of greater than approximately 90%, redundant. The plaintiff is correct. However, the Federal Circuit has stated, “[e]ven if the claim construction had rendered the dependent claim redundant, the doctrine of claim differentiation does not require us to give [claim terms] their broadest possible meaning. We may instead limit [claim terms] as demanded by the specification.” *Edward Life Sciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009) (citing *Nystrom v. TREX Co.*, 424 F.3d 1126, 1143 (Fed. Cir. 2005)). Thus, the court adopts the defendant’s proposed construction.

⁹ See footnote 2.

¹⁰ Id.